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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,060	12/26/2007	**Mark Parrington**	API-03-13-PCT-US	8643

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,060	PARRINGTON ET AL.	
	Examiner	Art Unit	
	JOANNE HAMA	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-47* is/are pending in the application.

4a) Of the above claim(s) *45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-44,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1 in the reply filed on April 2, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). With regard to the election of vectors that further comprise sequence that encode a tumor associated antigen or angiogenesis-associated antigen (claims 44, 45), Applicant elects tumor-associated antigen with traverse. With regard to the species election of claims 40-43, wherein the claims is drawn to vectors, Applicant elects ALVAC, avipox, and poxvirus vectors with traverse.

Claim 45 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 2, 2009.

Claims 1-37, 48-50 are cancelled.

Claims 38-44, 46, 47, drawn to an expression vector comprising a nucleic acid sequence of CAP(6D)-1,2 and human B7.1, are under consideration.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 -

1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

Figures 12 and 13 comprise nucleic acid sequences and no SEQ ID NOs. have been assigned to them. Each sequence must be assigned a SEQ ID NO. Further, each SEQ ID NO. must be provided by Applicant in computer readable format (CRF) and on paper, and a statement indicating that the sequences on the CRF and paper must be provided.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-44, 46, 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38, 39, 47 comprise the phrase, "as illustrated in Figure 12." Claims should not comprise language that refer to a figure or table, see MPEP 2173.05(s).

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m). Claims 40-44, 46 are included in the rejection as they depend on claims 38, 39.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-44, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlom et al., US Patent 6,045,802, in view of Matteucci, US Patent 4,923,808, patented May 8, 1990, Horig et al., 2000, Cancer Immunol. Immunother. 49: 504-514, Parmiani et al., 2002, J. Natl. Cancer Inst., 94: 805-818.

Schlom et al. teach a recombinant virus which has incorporated into its genome a gene encoding an antigen to a disease causing agent and a recombinant virus which

has incorporated into its genome a gene encoding an immunostimulatory molecule(s) for the purpose of stimulating an immune response against the disease causing agent (Schlom et al., abstract). Schlom et al. teach that several antigens are identified for use in recombinant vaccines for cancer therapies. One such antigen is human carcinoembryonic antigen (CEA) (Schlom et al., col. 2, lines 55-57). With regard to an immunostimulatory molecule, Schlom et al. teach the expression of the B7 gene family (Schlom et al., col. 3, 4th parag.). One B7 family member is B7.1 (Schlom et al. col. 7, line 46).

While Schlom et al. teach expression of CEA and B7.1 in a cancer vaccine, Schlom et al. do not teach SEQ ID NO. 6, a nucleic acid that encodes wild type human CEA protein.

Matteucci teaches that nucleic acids can comprise silent mutations and produce proteins at high yields (Matteucci, col. 2, 2nd parag.). Matteucci teaches that silent mutations are those in which a nucleotide change is not expressed as an amino acid change because of the degeneracy of the genetic code, while expressed mutations appear as changes in the amino acid sequence (Matteucci, col. 4, lines 1-5). Matteucci teaches that silent mutations are introduced in order to select for host organism codon preference, to remove bases which, when transcribed as mRNA would pair with other mRNA bases to form stem and loop structures that impede translation, or to achieve enhanced expression in other ways for which no theoretical basis has yet been advanced (Matteucci, col. 5, 1st parag.). It is noted that while Matteucci's title of the invention is to increasing secretion of secreted proteins, Matteucci teaches that silent

mutations act beneficially at the level of expression, rather than at the level of secretion (Matteucci, col. 5, lines 8-9). As such, Mateucci's teaching is not limited to translation of secreted proteins.

All of the component parts are taught by Schlom et al. and Matteucci. The only difference is the combination of the "old elements" into a single expression system comprising SEQ ID NO. 6 and a nucleic acid sequence encoding human B7.1. It would have been obvious for an artisan to take the wild type nucleic acid sequence of human CEA and to make silent mutations in the sequence. An artisan would have done so because Matteucci teaches that making silent mutations in a nucleic acid sequence increases the translation of protein.

It is noted that while Schlom et al. provide a working example of expressing CEA and B7 from separate vectors (see Examples 3-7), Schlom et al. teach that the genes can be inserted into one recombinant vector (Schlom et al., col. 1, under Field of the Invention)

With regard to the claims being drawn to viral vectors (claims 40-43), Schlom et al. teach that a number of viral vectors (including fowlpox virus) can be used (Schlom et al., col. 8, 2nd parag. under Virus Vectors). With regard to ALVAC vectors, the art at the time of filing teaches that artisan were actively using ALVAC vectors to express human CEA and B7.1 co-stimulatory molecule (e.g. see Horig et al.). As such, use of any viral vector, including that of ALVAC is a matter of design choice.

With regard to the claims being drawn to the vector further comprising one additional tumor associated antigen, it is noted that Schlom et al. teach that the vector

can express one or more antigens (Schlom et al., col., 1, line 19). The art recognizes that additional epitopes can be expressed from the vector as Parmiani et al., teach that human and animal tumors express multiple tumor-associated antigen (TAA) epitopes that are recognized by T cells and that some of the TAA epitopes can be lost or expressed at different times during tumor growth. As such, a vaccine against multiple TAA epitopes is more effective than a vaccine against a single epitope (Parmiani et al., page 808, 1st col., parag. under Single Epitope versus Polyepitope Vaccines). Given this teaching, an artisan would also include a second nucleic acid sequence encoding a tumor-associated antigen in order to generate an immune response to tumor cells when a particular epitope is expressed during a particular stage of tumor growth.

Thus, the claims are rejected.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Primary Examiner
Art Unit 1632

Application No.: 10/575,060

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing".

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the
"Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Figures 12 and 13 comprise nucleic acid sequences and no SEQ ID NOs. have been assigned to them. Each sequence must be assigned a SEQ ID NO. Further, each SEQ ID NO. must be provided by Applicant in computer readable format (CRF) and on paper, and a statement indicating that the sequences on the CRF and paper must be provided.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing". (If the unidentified sequences are not provided on the CRF)

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification. (If the unidentified sequences are not provided in the paper copy)

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). (If a new paper and/or CRF are required)

For questions regarding compliance to these requirements, please contact:

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